DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Re: CEREBYX®
Docket No. 96E-0442

#19

MAR 12 1997

RECEIVED

MAR 17 1997

PATENT EXTENSION
A/C PATENTS

The Honorable Bruce Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Box Pat. Ext.
Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Commissioner Lehman:

This is in regard to the application for patent term extension for U.S. Patent No. 4,260,769, filed by Warner-Lambert Company, under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for CEREBYX®, the human drug product claimed by the patent.

The total length of the regulatory review period for CEREBYX® is 3,748 days. Of this time, 3,218 days occurred during the testing phase and 530 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: May 4, 1986.

   FDA has verified the applicant's claim that the date the Investigational New Drug application became effective was on May 4, 1986.

2. The date the application was initially submitted with respect to the human drug product under subsection 505(b) of the Federal Food, Drug, and Cosmetic Act: February 23, 1995.

   The applicant claims July 14, 1994, as the date the New Drug Application (NDA) for CEREBYX® (NDA 20-450) was initially submitted. However, FDA records indicate that NDA 20-450, received by the Agency on July 15, 1994, was incomplete. The FDA refused this application and notified the applicant of this fact by letter dated September 12, 1994. The completed NDA was then received on February 23, 1995, which is considered to be the NDA initially submitted date.

3. The date the application was approved: August 5, 1996.

   FDA has verified the applicant's claim that NDA 20-450 was approved on August 5, 1996.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: Warner-Lambert Company / Patent Department
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